

# BEST AVAILABLE COPY

PCT

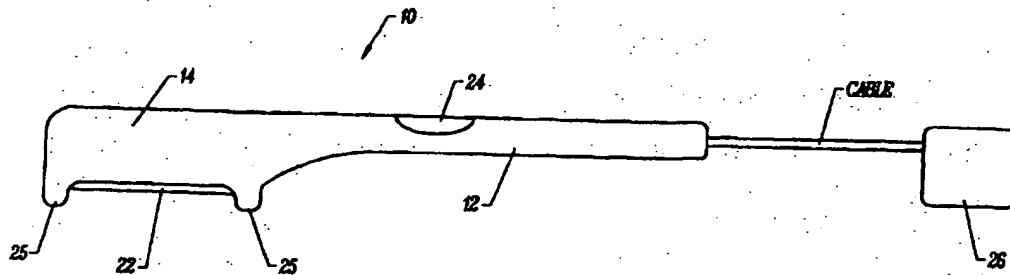
WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 1/40, A61B 17/32		A1	(11) International Publication Number: WO 98/07468 (43) International Publication Date: 26 February 1998 (26.02.98)
(21) International Application Number: PCT/US97/13044			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TT, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 6 August 1997 (06.08.97)			
(30) Priority Data: 08/700,196 20 August 1996 (20.08.96) US			
(60) Parent Application or Grant (63) Related by Continuation US Filed on 08/700,196 (CIP) 20 August 1996 (20.08.96)			
(71) Applicant (for all designated States except US): ORATEC INTERVENTIONS, INC. [US/US]; 3700 Haven Court, Menlo Park, CA 94025 (US).			Published With international search report.
(72) Inventors; and (75) Inventors/Applicants (for US only): FANTON, Gary [US/US]; 265 Golden Oak Drive, Portola Valley, CA 94028 (US). SHARKEY, Hugh [US/US]; 935 Corriente Pointe Drive, Redwood City, CA 94065 (US).			
(74) Agent: DAVIS, Paul; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).			

### (54) Title: APPARATUS FOR TREATING CHONDROMALICIA



### (57) Abstract

A thermal energy delivery apparatus (10) has a probe means (12) including a distal end and a proximal end. A first electrode means (22) is positioned at the distal end of the probe means. The first electrode means is configured to deliver sufficient thermal energy to a fibrillated cartilage surface to reduce a level of fibrillation of the fibrillated cartilage surface. A cabling means is coupled to the proximal end of the probe means.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LJ	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## APPARATUS FOR TREATING CHONDROMALICIA

BACKGROUND OF THE INVENTIONField of the Invention

This invention relates generally to a method and apparatus for treating chondromalacia, and more particularly to a method and apparatus that treats chondromalacia with minimal disruption of the cartilage bed of the knee.

Description of Related Art

The normal function of joints in humans depends on the distribution of relatively large forces across the body surfaces. In diarthrodial joints the magnitude of the joint forces reaches levels four to seven times body weight. These forces applied to joints are dispersed by articular cartilage. Cartilage function occurs via a highly organized extracellular matrix maintaining a fixed charge density and possessing a high affinity for water.

Normal articular cartilage consists of an assembly of large and small proteoglycans, collagens, hyaluronic acid and glycoproteins. These matrix macromolecules originate from chondrocytes localized in a nonrandom pattern through the cartilage matrix. In normal joints, chondrocytes do not proliferate; dividing chondrocytes indicate a change in cartilage homeostasis, either as regeneration or attempted repair.

Chondromalacia occurs when cartilage beds in joints become worn and strands of cartilage distended away from their respective cartilage beds and extend into the joint capsule. The cartilage surface becomes visibly disrupted, fissured and fibrillated. This has deteriorous effects on the mechanical properties of articular cartilage. This distension has been associated with knee pain. Treatment to date has included surgical intervention. In one arthroscopic procedure, a shaver is introduced through an arthroscope and is used to remove

the strands of disrupted and fibrillated cartilage. However, this treatment can disrupt and remove part of the normal cartilage bed and does not restore a smooth surface nor the mechanical function.

It would be desirable to provide a method and apparatus treating fibrillated cartilage joint surfaces or irregular cartilage joint surfaces by delivering sufficient thermal energy to reduce a level of fibrillation or irregularity of the fibrillated cartilage joint surface or the irregular cartilage joint surface. It would also be desirable to modify the fibrillated cartilage surface to a smooth surface. It would be further desirable to treat chondromalacia by reducing a level of fibrillation or irregularity of a fibrillated or irregular cartilage joint surface.

#### SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide a method and apparatus for treating fibrillated or irregular cartilage joint surfaces.

Another object of the invention is to provide a method and apparatus for delivering sufficient thermal energy to reduce a level of fibrillation of a fibrillated cartilage joint surface.

Yet another object of the invention is to provide a method and apparatus for delivering sufficient thermal energy to modify a fibrillated cartilage joint surface to a smooth surface.

A further object of the invention is to provide a method and apparatus for delivering sufficient thermal energy to modify an irregular cartilage joint surface to a smoother surface.

Still a further object of the invention is to provide a method and apparatus for delivering sufficient thermal energy to at least a portion of a plurality of cartilage strands coupled to a fibrillated cartilage surface, and melt the strands onto the fibrillated cartilage surface.

Another object of the invention is to provide a method and apparatus that uses thermal energy to treat chondromalacia.

These and other objects of the invention are achieved in a thermal energy delivery apparatus that has a probe means including a distal end and a proximal end. A first electrode means is positioned at the distal end of the probe means. The first electrode means is configured to deliver sufficient thermal energy to a fibrillated cartilage surface to reduce a level of fibrillation of the fibrillated cartilage surface. A cabling means is coupled to the proximal end of the probe means.

In one embodiment of the invention, an apparatus is configured to be positioned adjacent to a fibrillated cartilage joint surface. A probe means has a distal end and a proximal end. An insulator means has a first surface and a second surface. A first electrode means is positioned on the first surface of the insulator. The first electrode means has a first thermal energy delivery surface configured to deliver sufficient thermal energy to a plurality of cartilage strands coupled to the fibrillated cartilage joint surface to reduce a level of fibrillation of surface. A second electrode means is positioned on the second surface of the insulator. A cable means is coupled to the proximal end of the probe means.

In another embodiment, a method modifies a geometry of a fibrillated cartilage surface. A thermal energy delivery device is provided and includes a probe means with a distal end and a thermal energy delivery surface. A thermal energy source is also provided and coupled to the thermal energy delivery surface. The thermal energy delivery surface is positioned adjacent to the fibrillated cartilage surface in a non-contacting position. Sufficient thermal energy is delivered from the thermal energy delivery surface to reduce a level of fibrillation of the fibrillated cartilage surface.

The method and apparatus of the present invention can also be used to decrease the level of irregularity of an irregular cartilage surface.

The apparatus of the present invention may also include a sensor means positioned at the distal end of the probe means. A comparator means is provided and compares a measured temperature value at the sensor means with a predetermined temperature value. The comparator means generates a disabling

signal if the measured temperature value exceeds the predetermined maximum temperature value. A communication means is provided and communicates the disabling signal to the thermal energy source means to cease further delivery of energy from the thermal energy source means to the first electrode means.

In various embodiments of the invention, sufficient thermal energy is delivered from the thermal energy delivery surface to modify the fibrillated cartilage surface to a smooth surface. Thermal energy is delivered from the thermal energy delivery surface to create a less fibrillated, fibrillated cartilage surface. Thermal energy is delivered from the thermal energy delivery surface to cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to create a smoothened cartilage surface. Thermal energy is delivered from the thermal energy delivery surface to cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to melt onto the fibrillated cartilage surface. At least a portion of a plurality of cartilage strands are melted to create a smoothened cartilage surface.

#### BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective view of the apparatus of the present invention with a probe and two electrodes.

Figure 2 is a perspective view of the apparatus of the present invention with a probe, an electrode positioned at a distal end of the probe and two electrodes positioned on opposite sides of an insulator.

Figure 3 is a perspective view of a knee joint with chondromalacia.

Figure 4 is a perspective view of the apparatus of Figure 2 with a probe coiled distal end.

Figure 5 is a perspective view of the apparatus of the present invention with two electrodes positioned on opposite sides of an insulator.

Figure 6 is perspective view of the apparatus of the present invention including an electrode with radiused edges.

Figure 7 is a perspective view of the apparatus of the present invention including a rectangularly shaped electrode.

Figure 8 illustrates a perspective view of the apparatus of the present invention with electrodes formed on peripheral faces of the insulator.

Figure 9 is a cross-sectional view of the apparatus of Figure 8 taken along the lines 9-9.

Figure 10 is a perspective view of an electrode used with the apparatus of the present invention that is formed at a peripheral surface of the insulator and defines an interior non-conducting region.

Figure 11 is a perspective view of a toroidal electrode used with the apparatus of the present invention and defines an interior non-conducting region

Figure 12 is a perspective view of a non-circular toroidal electrode used with the apparatus of the present invention and defines an interior non-conducting region.

Figure 13 is a perspective view of a segmented electrode used with the apparatus of the present invention.

Figure 14 is a perspective view of a segmented toroidal electrode used with the apparatus of the present invention.

Figure 15 is a perspective view of a flexible probe used with the apparatus of the present invention.

Figure 16 is a block diagram illustrating a feedback system useful to control the temperature of electrodes of the present invention.

Figure 17 illustrates a circuit useful to implement the feedback system of Figure 16.

#### DETAILED DESCRIPTION

As shown in Figure 1, a thermal energy delivery apparatus 10 is configured to be positioned adjacent to, but spaced apart from a joint surface. Included is a probe 12 with a distal end 14, a first electrode 22 and a second electrode 24. Electrodes 22 and 24 can be operated in bipolar or monopolar.

Bipolar is preferred. A distancing element 25 distances a thermal energy delivery surface of electrode 22 from the joint surface. Preferably, the thermal energy delivery surface of electrode 22, or of electrode 24, does not touch the joint surface. As illustrated in Figure 1, distancing element 25 is included. In other embodiments, distancing element 25 is not included and the thermal energy delivery surface of electrode 22 or of electrode 24 are positioned directly on the joint surface.

Referring now to Figure 2, thermal energy delivery apparatus 10 is configured to be positioned and deliver thermal energy to a joint surface. Apparatus 10 includes probe 12 with distal end 14 and an insulator 16 including first and second surfaces 18 and 20 formed on opposite sides on insulator 16. A pair of electrodes are also provided. First electrode 22 is positioned on first surface 18 of insulator 16. Second electrode 24 is positioned on second surface 20 of insulator 16. Thermal energy source 26 is coupled to first electrode 22 and second electrode 24 with a cable.

Insulator 16 can be an elongated structure with a longitudinal axis. Surfaces 18 and 20 can be parallel to each other. Insulator can be made of a variety of insulating materials known to those skilled in the art. Insulator 16 need not be one integral unit and surfaces 18 and 20 can be made of separate insulators that are separated. Surfaces 18 and 20 can be planar, non-planar and have geometries that conform closely to interior joint surfaces. In one embodiment, the dimensions of distal end 14 are sufficiently small to be positioned on a joint surface.

A knee joint surface 28 is shown in Figure 3. Knee joint surface 28 is defined by a first cartilage bed 30 formed at a distal end of the femur, and a second cartilage bed 32 formed at a distal end of the tibia. The present invention is not limited to the knee joint surface and can be used in a variety of different joint surfaces. Any joint surface susceptible to chondromalacia is treatable with apparatus 10. The present invention is suitable for the treatment of fibrillated cartilage joint surfaces to reduce the level of fibrillation and create smoother

surfaces. The present invention is also used to treat irregular joint surfaces, where there are peaks and valleys, and create a less irregular joint surface. In certain embodiments, the irregular joint surface becomes a smooth joint surface.

A first plurality of cartilage strands 34 are coupled to first cartilage bed 30 and have become dislodged and dangle in joint surface 28. A second plurality of cartilage strands 36 are connected to second cartilage bed 32. Second plurality of cartilage strands 36 have also become dislodged and dangle in joint surface 28.

In one embodiment of the invention, a method is provided that modifies a geometry of a fibrillated cartilage surface. Sufficient thermal energy is delivered from first electrode 22 or second electrode 24 at different times to reduce a level of fibrillation of the fibrillated cartilage joint surface. In various embodiments of the invention, sufficient thermal energy is delivered electrode 22 or 24 to, (i) change the fibrillated cartilage surface to a smooth or smoother surface, (ii) reduce a level of fibrillation of the fibrillated cartilage surface, (iii) cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to create a smoothed cartilage surface, (iv) cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to melt onto the fibrillated cartilage surface or (v) melt at least a portion of a plurality of cartilage strands to create a smoothed cartilage surface.

First electrode 22 has a first thermal energy delivery surface configured to deliver thermal energy to cartilage strands 34 and second electrode 24 has a second thermal energy delivery surface configured to deliver thermal energy to cartilage strands 36. Thermal energy includes but is not limited to RF, microwave, resistive heating, ultrasound, coherent or incoherent light and a thermal jet source. By delivering the appropriate amount of thermal energy to joint surface 28, strands 34 and 36 move out of joint surface 28 and the surfaces of cartilage beds 30 and 32 are smoothed. Additionally, delivered thermal energy can remove some or substantially all of cartilage strands 34 and 36 from joint surface 28. The delivery of thermal energy physically smooths the surface.

of cartilage beds 30 and 32, changes the ultrastructure of the cartilage, stimulates cartilage replication and growth and changes the chemical environment in joint surface 28 and cartilage beds 30 and 32 to relieve pain.

Apparatus 10 is used to modify the geometry of cartilage strands 34 and 36 through cartilage shrinkage and possibly limited ablation of strands 34 and 36. Distal end 14 of probe 12 is inserted through an arthroscope to joint surface 28. First and second electrodes 22 and 24 are introduced into joint surface 28. Sufficient thermal energy is delivered from electrodes 22 and 24 to shrink at least a portion of cartilage strands 34 and 36, causing the strands to lie down on cartilage beds 30 and 32. The delivery of thermal energy to joint surface 28 results in an "ironing" of cartilage strands 34 and 36 onto cartilage beds 30 and 32.

Sufficient thermal energy is delivered from first and second electrodes 22 and 24 to shrink at least a portion of cartilage strands 34 and 36 without ablating more than 25% of cartilage beds 30 and 32. In one embodiment, sufficient energy is delivered by first and second electrodes 22 and 24 to raise the temperature of joint surface in the range of 45 to 90 degrees C, preferably 45 to 75 degrees C and more preferably 50 to 70 degrees C. Maintenance of a suitable temperature, and the delivery of thermal energy to joint surface 28, is sufficient to cause strands 34 and 36 to become at least partially melted onto the cartilage joint surface while minimizing ablation of cartilage beds 30 and 32.

Insulator 26 and first and second electrodes 22 and 24 are configured to be inserted into joint surface 28. Probe 12 is moved back and forth through joint surface 28 to deliver a sufficient amount of thermal energy to strands 34 and 36 to cause them to lie down on their respective cartilage beds. The thermal energy delivery surfaces of first and second electrodes 22 and 24 can move along the surfaces of cartilage beds 30 and 32 to complete the ironing effect.

Referring now to Figure 4, distal end 14 of probe 12 can have a coiled geometry as well as a variety of geometric configurations. Preferably, distal end 14 is malleable or sufficiently flexible to impart movement of first and second

electrodes 22 and 24. Distal end 14 can pivot, be hinged, be articulated, or made of a shaped memory metal, and the like, in order to enable first and second electrodes 22 and 24 to follow the contours of joint surface 28.

As shown in Figure 5, first and second electrodes 22 and 24 can be operated in a bipolar mode. This concentrates the flow of RF energy between first and second electrodes 22 and 24 and diverts direct RF energy flow away from cartilage beds 30 and 32. RF energy which is directed between first and second electrodes 22 and 24 heats up fluids within joint surface 28 and provides a more controlled delivery of energy to cartilage strands 34 and 36. RF ablation of cartilage beds 30 and 32 is reduced.

First and second electrodes 22 and 24 can have a variety of different geometric configurations. As illustrated in Figure 6, first and second electrodes 22 and 24 are symmetrically shaped with radiused edges. Elimination of sharp edges at an electrode surface reduce the creation of hot spots of thermal energy delivered to a site. In Figure 7, first and second electrodes 22 and 24 have rectangular geometries with non-radiused edges. First and second electrodes 22 and 24 can each have different sizes and geometries. First and second electrodes 22 and 24 can be mirror images of each other or they can be different.

Referring now to Figure 8, first and second electrodes 22 and 24 are formed on a periphery of insulation surfaces 18 and 20 respectively. In this embodiment, each electrode 22 and 24 defines a first and a second non-conducting region 38 and 40 on an insulator surface 18 and 20 within an interior of first and second electrodes 18 and 20. Non-conducting regions 38 and 40 can be the actual surface of insulator 16, or may be additional structures, each with a non-conducting surface, that are formed on insulation surfaces 18 and 20.

First and second sensors 42 and 44 can be provided and associated with first and second electrodes 22 and 24 to measure temperature and/or impedance. First and second sensors 42 and 44 are positioned on a surface of first and second electrodes 22 and 24, on a surface of probe 12, on non-conducting

regions 38 and 40, or can be advanced and retracted from distal end 14 to and from joint surface 28.

First and second sensors 42 and 44 are of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. Suitable thermal sensors 42 and 44 include a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. Sensors 42 and 44 need not be thermal sensors.

Sensors 42 and 44 measure temperature and/or impedance to permit monitoring and a desired level of energy delivered determined. This reduces ablation damage to cartilage beds 30 and 32. If at any time sensor 42 or 44 determines that a desired temperature is exceeded, then an appropriate feedback signal is received at thermal energy source 26 which then regulates the amount of energy delivered to first and second electrodes 22 and 24.

Sensors 42 and 44 are positioned on non-conducting regions 38 and 40 in Figure 9. Non-conducting regions 38 and 40 have a variety of geometric surfaces including but not limited to planar, non-planar, concave, convex, and the like. In one embodiment, non-conducting regions 38 and 40 are closer to the midline of insulator 16 than first and second electrodes 22 and 24. This enhances the bipolar conduction of thermal energy between electrodes 22 and 24 in the bipolar mode of operation.

First and second electrodes 22 and 24 can have various geometries including but not limited to cylindrical, semi-cylindrical, rectangular, cubic, irregularly shaped, toroidal (Figure 10), non-circular toroidal (Figure 11), non-symmetrical, non-symmetrical toroidal (Figure 12) or be segmented and capable of multiplexing (Figures 13 and 14). In one embodiment, first electrode 22 has a toroidal geometry, first sensor 42 is positioned on non-conducting region 38, and distal end 14 is flexible and curved.

Figure 16 illustrates a block diagram of a temperature/impedance feedback system useful with apparatus 10. Thermal energy is delivered to first and second electrodes 22 and 24 by thermal energy source 26, and applied to

cartilage strands 34 and 36. A monitor 56 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value a disabling signal 48 is transmitted to thermal energy source 26, ceasing further delivery of thermal energy to first and second electrodes 22 and 24. If measured impedance is within acceptable limits, energy continues to be applied. During the application of thermal energy to cartilage strands 34 and 36, sensor 42 measures the temperature at the surface of sensor 42. A comparator 50 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 50 sends a signal to thermal energy source 26 to continue sending thermal energy, to increase or decrease the level of delivered thermal energy, or to cease delivery of thermal energy.

An output 52 from temperature comparator 50 can be input to thermal energy source 26 to regulate the amount of power delivered. Output 54 from impedance monitor 56 can be input to control the temperature at joint surface 28.

Referring now to Figure 17, thermal energy source 26 is coupled to first and second electrodes 22 and 24 and apply a biologically safe voltage to cartilage strands 34 and 36. In the embodiment illustrated in Figure 11, apparatus 10 is represented as a bipolar ablation device. First and second electrodes 22 and 24 are connected to a primary side of transformer windings 58 and 60. The common primary windings 58 and 60 are magnetically coupled with a transformer core to secondary windings 58' and 60'.

The primary windings 58 of the first transformer  $t_1$  couple the output voltage of apparatus 10 to the secondary windings 58'. The primary windings 60 of the second transformer  $t_2$  couple the output current of ablation apparatus 10 to the secondary windings 60'.

Measuring circuits determine the root mean square (RMS) values or magnitudes of the current and voltage. These values, represented as voltages, are inputted to a diving circuit D to geometrically calculate, by dividing the RMS

voltage value by the RMS current value, the impedance of the tissue site at sensor 42.

The output voltage of the divider circuit D is presented at the positive (+) input terminal of comparator A. A voltage source  $V_o$  supplies a voltage across the variable resistor  $R_o$ , thus allowing one to manually adjust the voltage presented at the negative input of comparator A. This voltage represents a maximum impedance value beyond which power will not be applied to electrode 22. Specifically, once the tissue is heated to a temperature corresponding to an impedance value greater than the maximum cut-off impedance, thermal energy source 26 stops supplying energy to first and second electrodes 22 and 24. Comparator A can be of any of a commercially available type that is able to control the amplitude or pulse width modulation of thermal energy source 26.

The temperature within joint surface 28 can be controlled based on the tissue impedance, as represented by signal 62, or based on tissue temperature, as represented by signal 64. In one embodiment, the switch S is activated to allow the impedance signal 62 to enter the positive (+) input terminal of comparator A. This signal along with the reference voltage applied to the negative (-) input terminal actuates comparator A to produce an output signal. If the selected tissue ablation site is heated to a biologically damaging temperature, the tissue impedance will exceed a selected impedance value seen at the negative (-) input terminal, thereby generating disabling signal 48 to disable thermal energy source 26, ceasing the energy supplied to first and second electrodes 22 and 24.

The output signal of comparator A may either disable thermal energy source's 26 energy output, depending on the tissue temperature as reflected by its impedance.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this

art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A thermal energy delivery apparatus, comprising:  
a probe means including a distal end and a proximal end;  
a first electrode means positioned at the distal end of the probe means,  
wherein the first electrode means is configured to deliver sufficient thermal  
energy to a fibrillated cartilage surface to reduce a level of fibrillation of the  
fibrillated cartilage surface; and  
a cabling means coupled to the proximal end of the probe means.
2. The apparatus of claim 1, further comprising:  
means for distancing the first electrode means from the fibrillated  
cartilage surface.
3. The apparatus of claim 1, further comprising:  
an offset member means positioned at the distal end of the probe means  
and configured to distance the first electrode means from the fibrillated cartilage  
surface.
4. The apparatus of claim 1, further comprising:  
a second electrode means positioned on the probe means.
5. The apparatus of claim 1, wherein the apparatus is a bipolar  
device.
6. The apparatus of claim 1, wherein the apparatus is a monopolar  
device.

1           7. The apparatus of claim 1, wherein the first and second electrode  
2           means are configured to minimize damage to a cartilage bed underlying the  
3           fibrillated cartilage surface.

1           8. The apparatus of claim 7, further comprising:  
2           a sensor means positioned at the distal end of the probe means.

1           9. The apparatus of claim 1, further comprising:  
2           a thermal energy source means coupled to the cabling means.

1           10. The apparatus of claim 1, wherein the thermal energy source is  
2           selected from RF, microwave, resistive heating, ultrasound, coherent or  
3           incoherent light and a liquid thermal jet.

1           11. The apparatus of claim 1, wherein the distal end of the probe  
2           means is sized to contract a joint.

1           12. The apparatus of claim 1, wherein the distal end of the probe  
2           means is sized to contract an articulated joint.

1           13. The apparatus of claim 9, further comprising:  
2           a sensor means positioned at the distal end of the probe means;  
3           a comparator means configured for comparing a measured temperature  
4           value at the sensor means with a predetermined temperature value and  
5           generating a disabling signal if the measured temperature value exceeds the  
6           predetermined maximum temperature value; and  
7           a communication means for communicating the disabling signal to the  
8           thermal energy source means to cease further delivery of energy from the  
9           thermal energy source means to the first electrode means.

14. A thermal energy delivery apparatus, comprising:  
a probe means including a distal end and a proximal end;  
a first thermal energy delivery surface positioned at one side of the distal  
end of the probe means, wherein the first thermal energy delivery surface is  
configured to deliver sufficient thermal energy to a fibrillated cartilage surface to  
reduce a level of fibrillation of the fibrillated cartilage surface;

a thermal energy insulator positioned adjacent to the first thermal energy  
delivery surface on an opposing second side of the distal end of the probe means;  
and

a cabling means coupled to the proximal end of the probe means.

15. A thermal energy delivery apparatus, comprising:  
a probe means including a distal end and a proximal end;  
a first electrode means positioned at the distal end of the probe means,  
wherein the first electrode means is configured to deliver sufficient thermal  
energy to an irregular cartilage surface to reduce a level of irregularity of the  
fibrillated cartilage surface; and

a cabling means coupled to the proximal end of the probe means.

16. An apparatus configured to be positioned adjacent to a fibrillated  
cartilage joint surface, comprising:

a probe means with a distal end and a proximal end;  
an insulator means with a first surface and a second surface;  
a first electrode means positioned on the first surface of the insulator with  
a first thermal energy delivery surface configured to deliver sufficient thermal  
energy to a plurality of cartilage strands coupled to the fibrillated cartilage joint  
surface to reduce a level of fibrillation of the fibrillated cartilage joint surface;

a second electrode means positioned on the second surface of the  
insulator; and

a cable means coupled to the proximal end of the probe means.

1           17. The apparatus of claim 16, further comprising:  
2           a thermal energy source means coupled to the first electrode means.

1           18. The apparatus of claim 17, wherein the thermal energy source is  
2           selected from RF, microwave, resistive heating, ultrasound, coherent or  
3           incoherent light and a liquid thermal jet.

1           19. The apparatus of claim 17, wherein the thermal energy source  
2           means is coupled to the second electrode means.

1           20. The apparatus of claim 16, wherein the distal end of the probe  
2           means is sized to contract a joint.

1           21. The apparatus of claim 16, wherein the distal end of the probe  
2           means is sized to contract an articulated joint.

1           22. The apparatus of claim 16, wherein the first electrode means is  
2           formed on a periphery of a first surface of the insulator and defines a first non-  
3           conducting region between the first electrode means.

1           23. The apparatus of claim 22, wherein the second electrode means is  
2           formed on a periphery of an opposing second surface of the insulator means and  
3           defines a second non-conducting region between the second electrode means.

1           24. The apparatus of claim 16, wherein the first electrode means has a  
2           toroidal geometry defining a first non-conducting interior region.

1           25. The apparatus of claim 16, wherein the first electrode means has a  
2           non-circular toroidal geometry defining a first non-conducting interior region.

26. The apparatus of claim 16, wherein the first electrode means has a segmented toroidal geometry defining a first non-conducting interior region.

27. The apparatus of claim 16, wherein the first electrode means has a segmented non-circular toroidal geometry defining a first non-conducting interior region.

28. The apparatus of claim 23, wherein the second electrode means has a toroidal geometry defining a second non-conducting interior region.

29. The apparatus of claim 23, wherein the second electrode means has a non-circular toroidal geometry defining a second non-conducting interior region.

30. The apparatus of claim 23, wherein the second electrode means has a segmented toroidal geometry defining a second non-conducting interior region.

31. The apparatus of claim 23, wherein the second electrode means has a segmented non-circular toroidal geometry defining a second non-conducting interior region.

32. The apparatus of claim 22, wherein the first non-conducting interior region has a concave surface.

33. The apparatus of claim 23, wherein the second non-conducting interior region has a concave surface.

1           34. The apparatus of claim 22, wherein a first sensor means is  
2           positioned at the first non-conducting interior region.

1           35. The apparatus of claim 23, wherein a second sensor means is  
2           positioned at the second non-conducting interior region.

1           36. The apparatus of claim 16, wherein at least a portion of the probe  
2           means is malleable.

1           37. The apparatus of claim 16, wherein the first and second electrode  
2           means operate in a bipolar mode.

1           38. The apparatus of claim 16, wherein the first and second electrode  
2           means operate in a monopolar mode.

1           39. The apparatus of claim 17, further comprising:  
2           a sensor means positioned at the distal end of the probe means;  
3           a comparator means for comparing a measured temperature value at the  
4           sensor means with a predetermined temperature value and generating a disabling  
5           signal if the measured temperature value exceeds the predetermined maximum  
6           temperature value; and  
7           a communication means for communicating the disabling signal to the  
8           thermal energy source means to cease further delivery of energy from the  
9           thermal energy source means to the first electrode means.

1           40. A method for modifying a geometry of a fibrillated cartilage  
2           surface, comprising:

3           providing a thermal energy delivery device including a probe means with  
4           a distal end and a thermal energy delivery surface;

providing a thermal energy source coupled to the thermal energy delivery surface;

positioning the thermal energy delivery surface adjacent to the fibrillated cartilage surface; and

delivering sufficient thermal energy from the thermal energy delivery to reduce a level of fibrillation of the fibrillated cartilage surface.

41. The method of claim 40, wherein sufficient thermal energy is delivered from the thermal energy delivery surface to modify the fibrillated cartilage surface to a smooth surface.

42. The method of claim 40, wherein sufficient thermal energy is delivered from the thermal energy delivery surface to create a less fibrillated, fibrillated cartilage surface.

43. The method of claim 40, wherein sufficient thermal energy is delivered from the thermal energy delivery surface to cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to create a smoothened cartilage surface.

44. The method of claim 40, wherein sufficient thermal energy is delivered from the thermal energy delivery surface to cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to melt onto the fibrillated cartilage surface.

45. The method of claim 37, wherein a melting of at least a portion of a plurality of cartilage strands creates a smoothened cartilage surface.

46. The method of claim 40, wherein the thermal energy delivery surface remains distanced from the fibrillated cartilage surface.

1           47. The method of claim 40, further comprising:  
2           measuring a temperature of an area adjacent to the fibrillated cartilage  
3           surface with a sensor;  
4           comparing a measured temperature at the area adjacent to the fibrillated  
5           cartilage surface to a predetermined temperature value and generate a signal  
6           representative of a difference between the measured temperature and the  
7           predetermined temperature value; and  
8           transmitting to the thermal energy source a signal to cease further  
9           thermal energy delivery if the measured temperature exceeds the predetermined  
10           temperature.

1           48. The method of claim 40, wherein the thermal energy source is an  
2           RF source.

1           49. The method of claim 40, wherein the thermal energy source is a  
2           microwave source.

1           50. The method of claim 40, wherein the thermal energy source is a  
2           resistive heating source.

1           51. The method of claim 40, wherein the thermal energy source is an  
2           ultrasonic source.

1           52. The method of claim 40, wherein the thermal energy source is a  
2           coherent or incoherent light source.

1           53. The method of claim 40, wherein the thermal energy source is a  
2           liquid thermal jet source.

1           54. A method for treating chondromalacia on a joint surface,  
2           comprising:  
3            providing a thermal energy delivery device including a probe means with  
4            a distal end and a thermal energy delivery surface;  
5            providing a thermal energy source coupled to the thermal energy delivery  
6            surface;  
7            positioning the thermal energy delivery surface adjacent and distanced  
8            from a fibrillated cartilage joint surface; and  
9            delivering sufficient thermal energy from the thermal energy delivery  
0            device to reduce a level of fibrillation of the fibrillated cartilage joint surface.

1           55. The method of claim 54, wherein sufficient thermal energy is  
2           delivered from the thermal energy delivery surface to modify the fibrillated  
3           cartilage joint surface to a smooth surface.

1           56. The method of claim 54, wherein sufficient thermal energy is  
2           delivered from the thermal energy delivery surface to create a less fibrillated,  
3           fibrillated cartilage joint surface.

1           57. The method of claim 54, wherein sufficient thermal energy is  
2           delivered from the thermal energy delivery surface to cause at least a portion of a  
3           plurality of cartilage strands coupled to the fibrillated cartilage joint surface to  
4           create a smoothed cartilage joint surface.

1           58. The method of claim 54, wherein sufficient thermal energy is  
2           delivered from the thermal energy delivery surface to cause at least a portion of a  
3           plurality of cartilage strands coupled to the fibrillated cartilage joint surface to  
4           melt onto the fibrillated cartilage joint surface.

1           59. The method of claim 58, wherein a melting of at least a portion of  
2           a plurality of cartilage strands creates a smoothed cartilage joint surface.

1           60. The method of claim 54, wherein the thermal energy delivery  
2           surface remains distanced from the fibrillated cartilage joint surface.

1           61. The method of claim 54, further comprising:  
2           measuring a temperature of an area adjacent to the fibrillated cartilage  
3           joint surface with a sensor;  
4           comparing a measured temperature at the area adjacent to the fibrillated  
5           cartilage joint surface to a predetermined temperature value and generate a signal  
6           representative of a difference between the measured temperature and the  
7           predetermined temperature value; and  
8           transmitting to the thermal energy source a signal to cease further  
9           thermal energy delivery if the measured temperature exceeds the predetermined  
10           temperature.

1           62. A method for treating chondromalacia on a joint surface,  
2           comprising:

3           providing a thermal energy delivery device including a probe means with  
4           a distal end and a thermal energy delivery surface;  
5           providing a thermal energy source coupled to the thermal energy delivery  
6           surface;  
7           positioning the thermal energy delivery surface on a fibrillated cartilage  
8           joint surface; and  
9           delivering sufficient thermal energy from the thermal energy delivery  
0           device to reduce a level of fibrillation of the fibrillated cartilage joint surface.

1           63. A method for treating chondromalacia on a joint surface,  
2           comprising:

providing a thermal energy delivery device including a probe means with a distal end and a thermal energy delivery surface;

providing a thermal energy source coupled to the thermal energy delivery surface;

positioning the thermal energy delivery surface adjacent and distanced from an irregular cartilage joint surface; and

delivering sufficient thermal energy from the thermal energy delivery device to reduce a level of irregularity of the irregular cartilage joint surface.

1/7

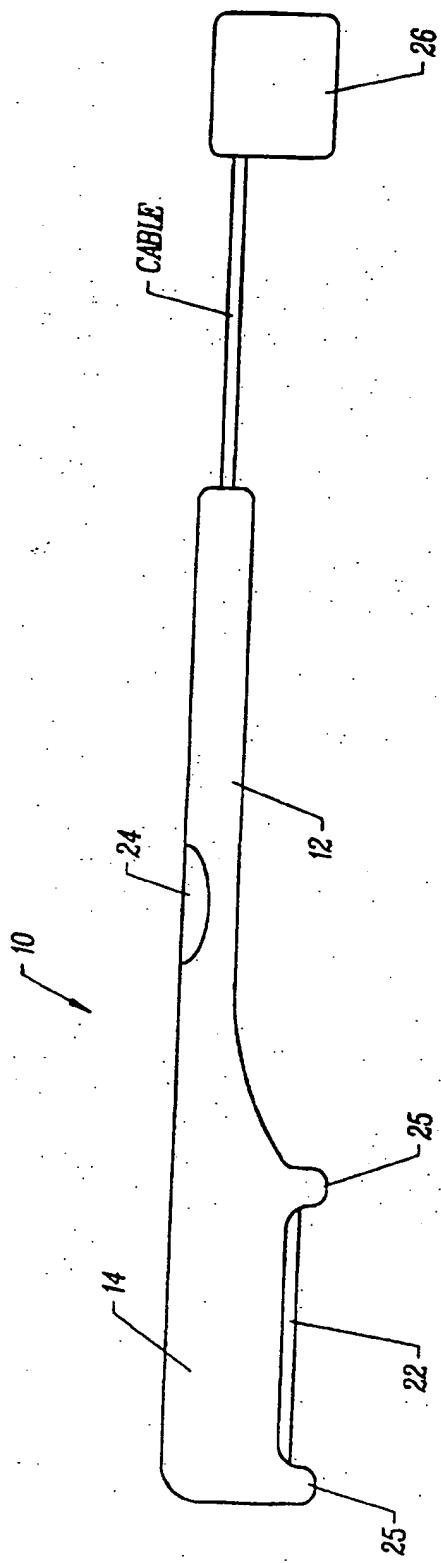


FIG. 1

2/7

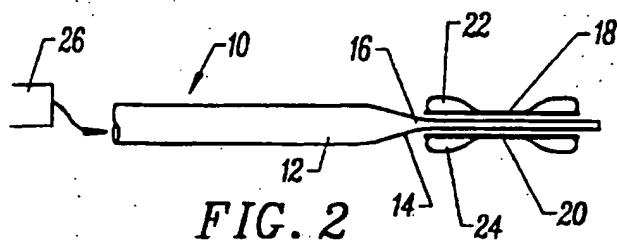


FIG. 2

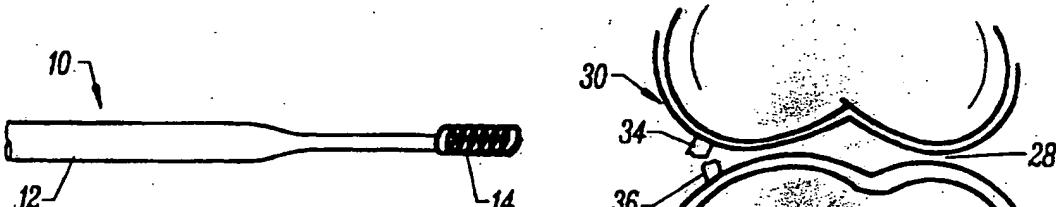


FIG. 4

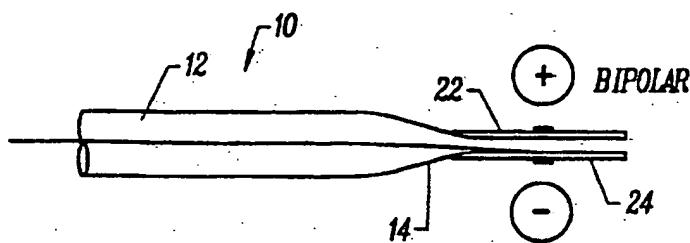


FIG. 5

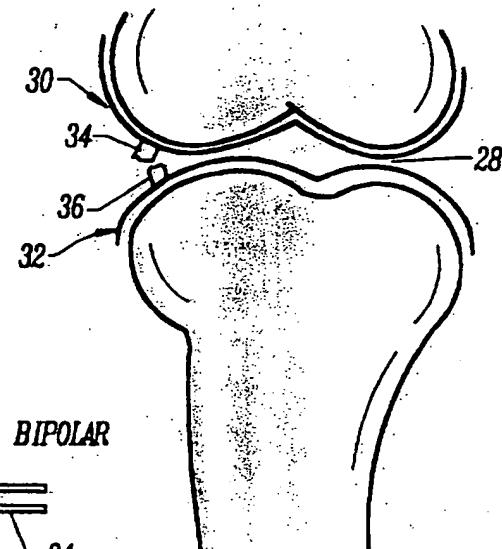


FIG. 3

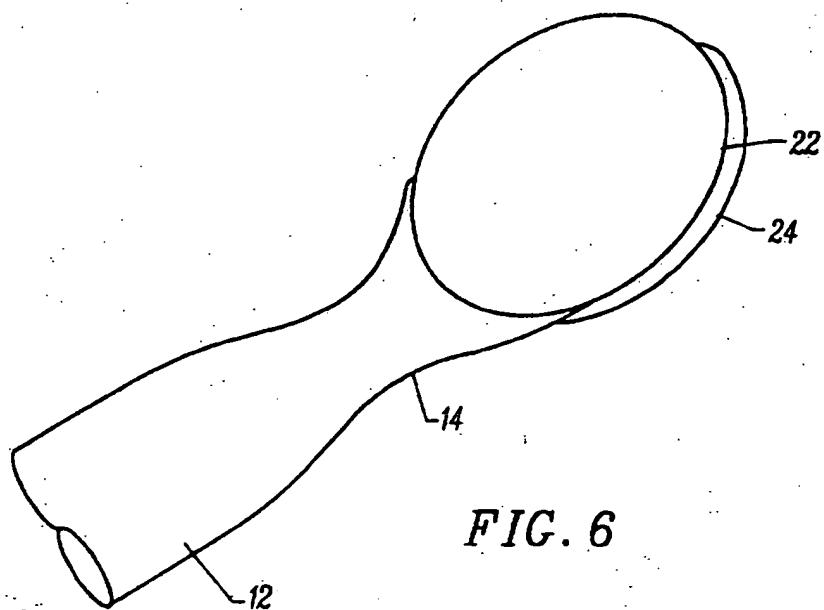


FIG. 6

3/7

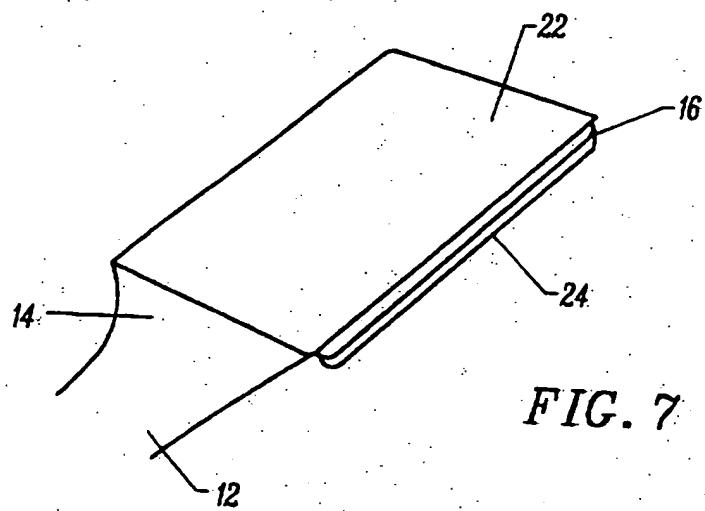


FIG. 7

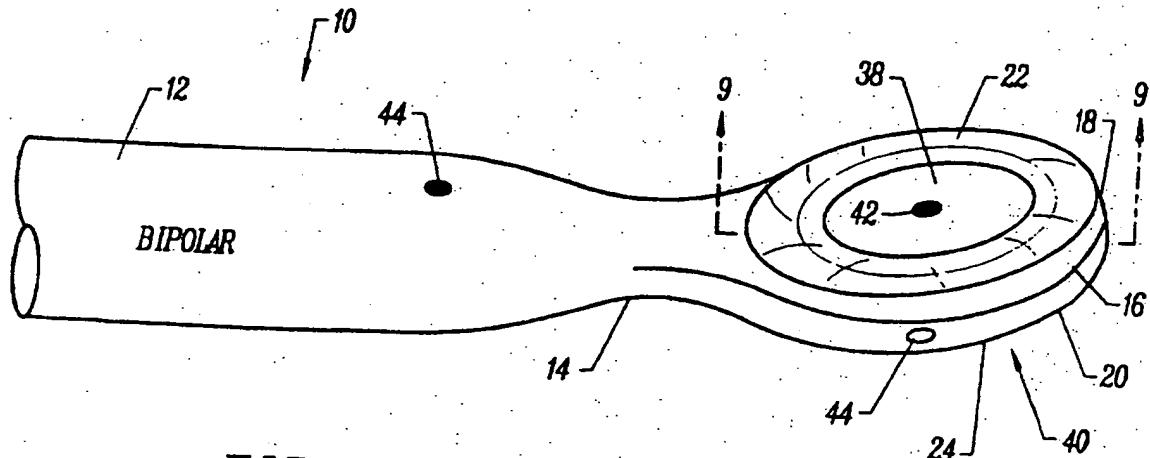


FIG. 8

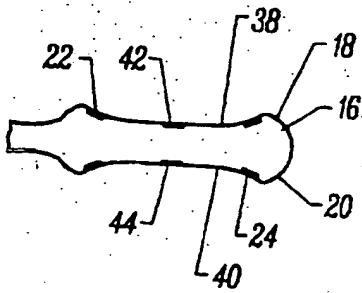
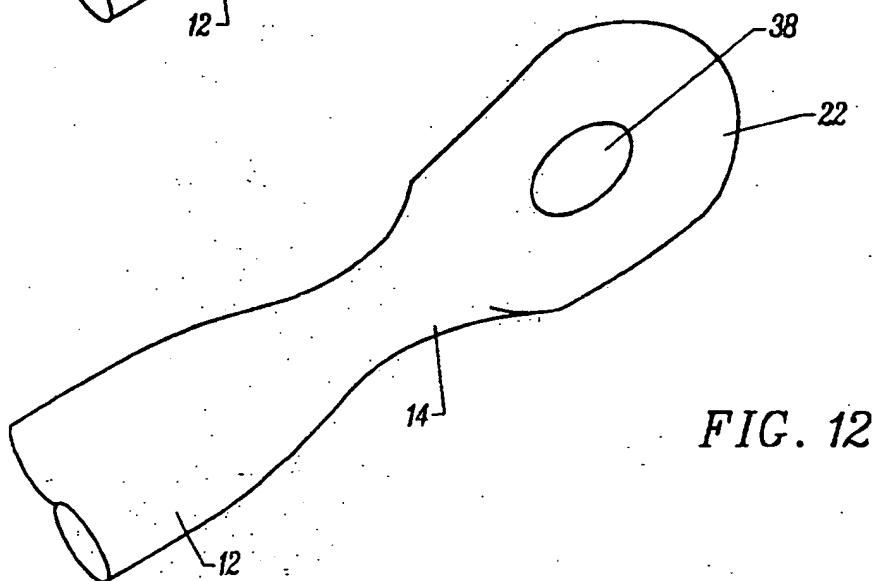
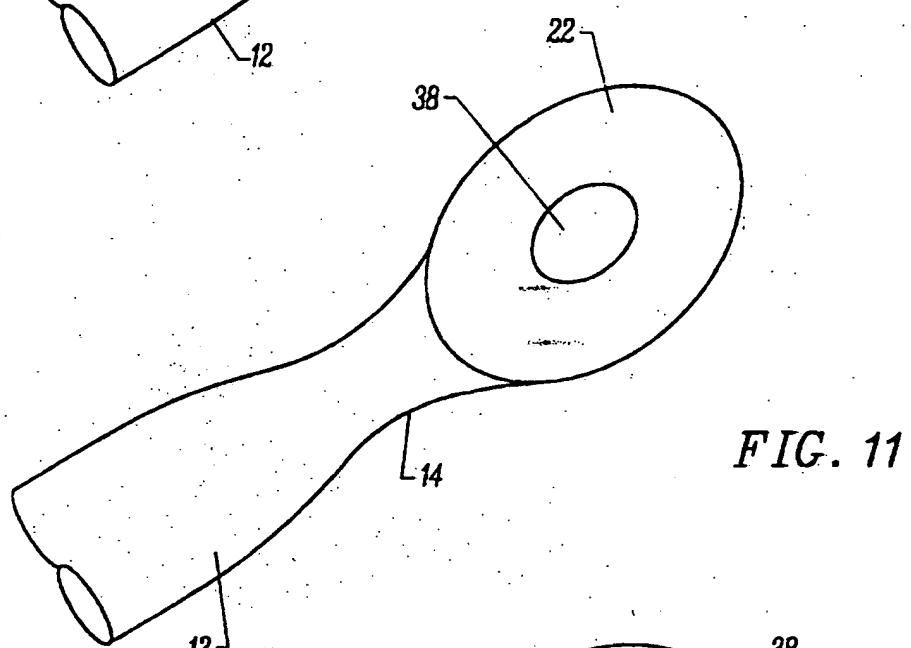
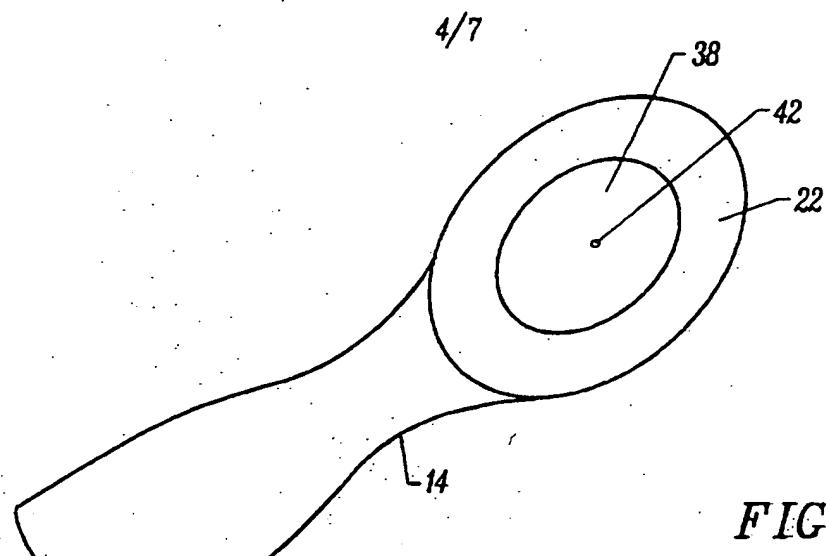


FIG. 9



5/7

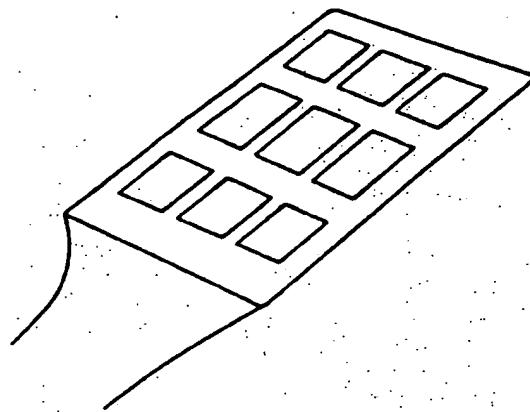


FIG. 13

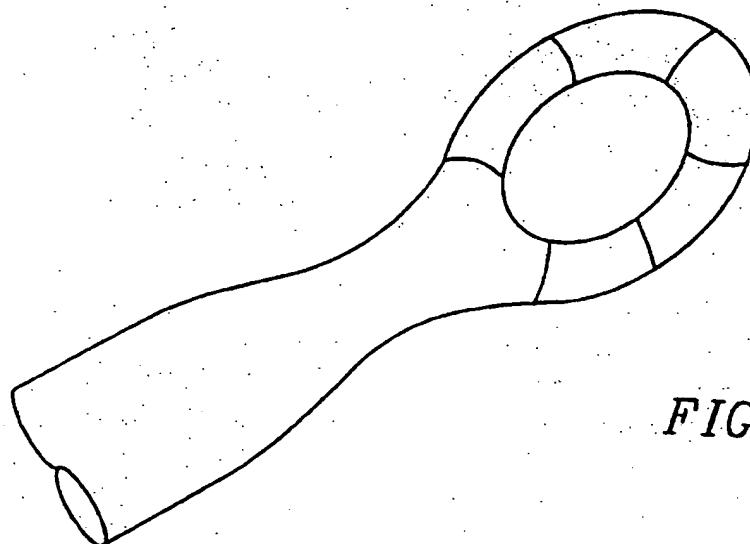


FIG. 14

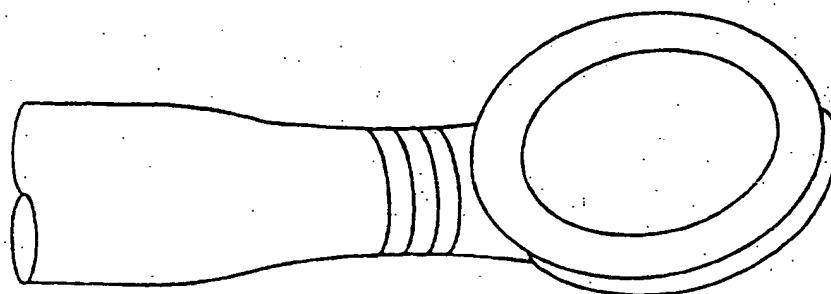


FIG. 15

6/7

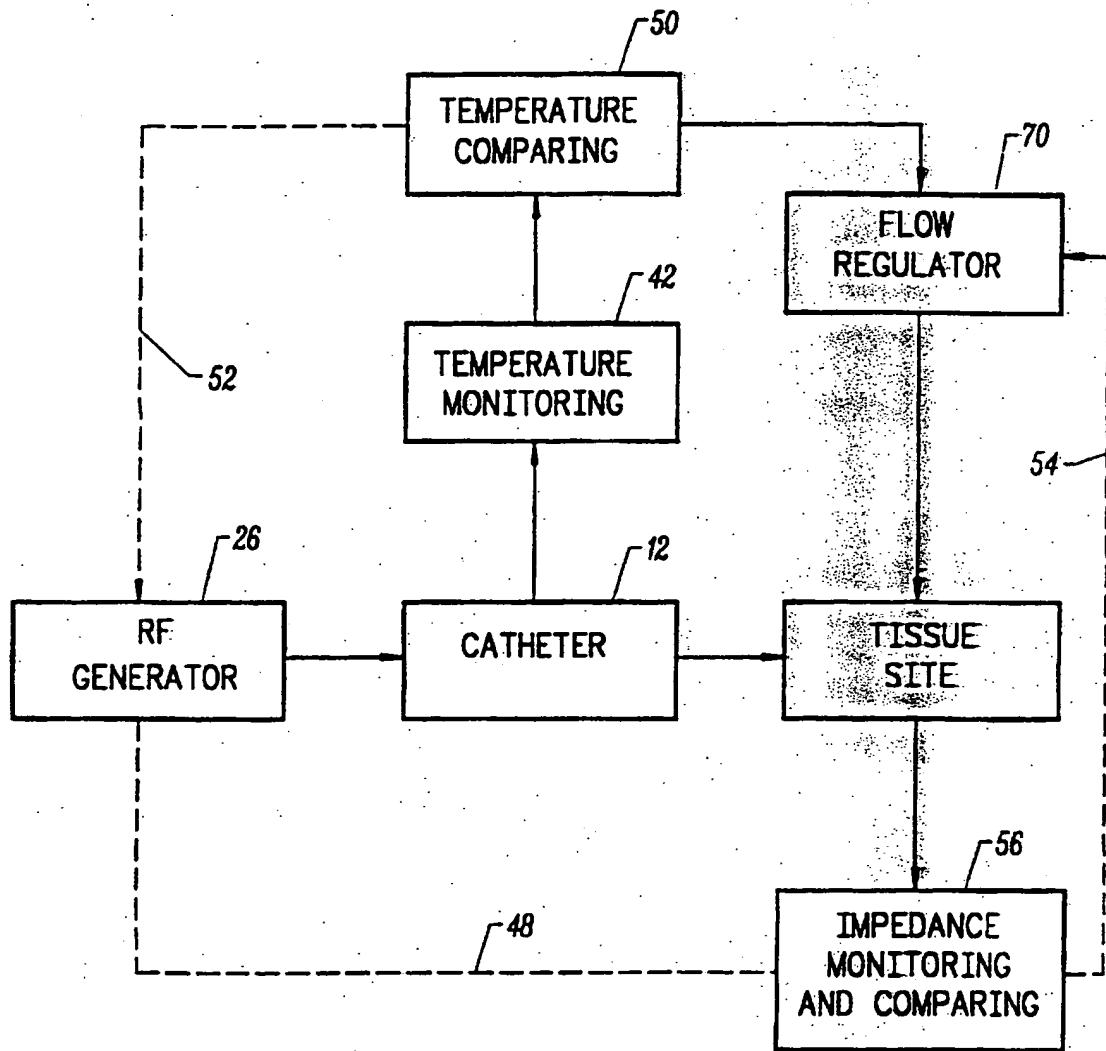
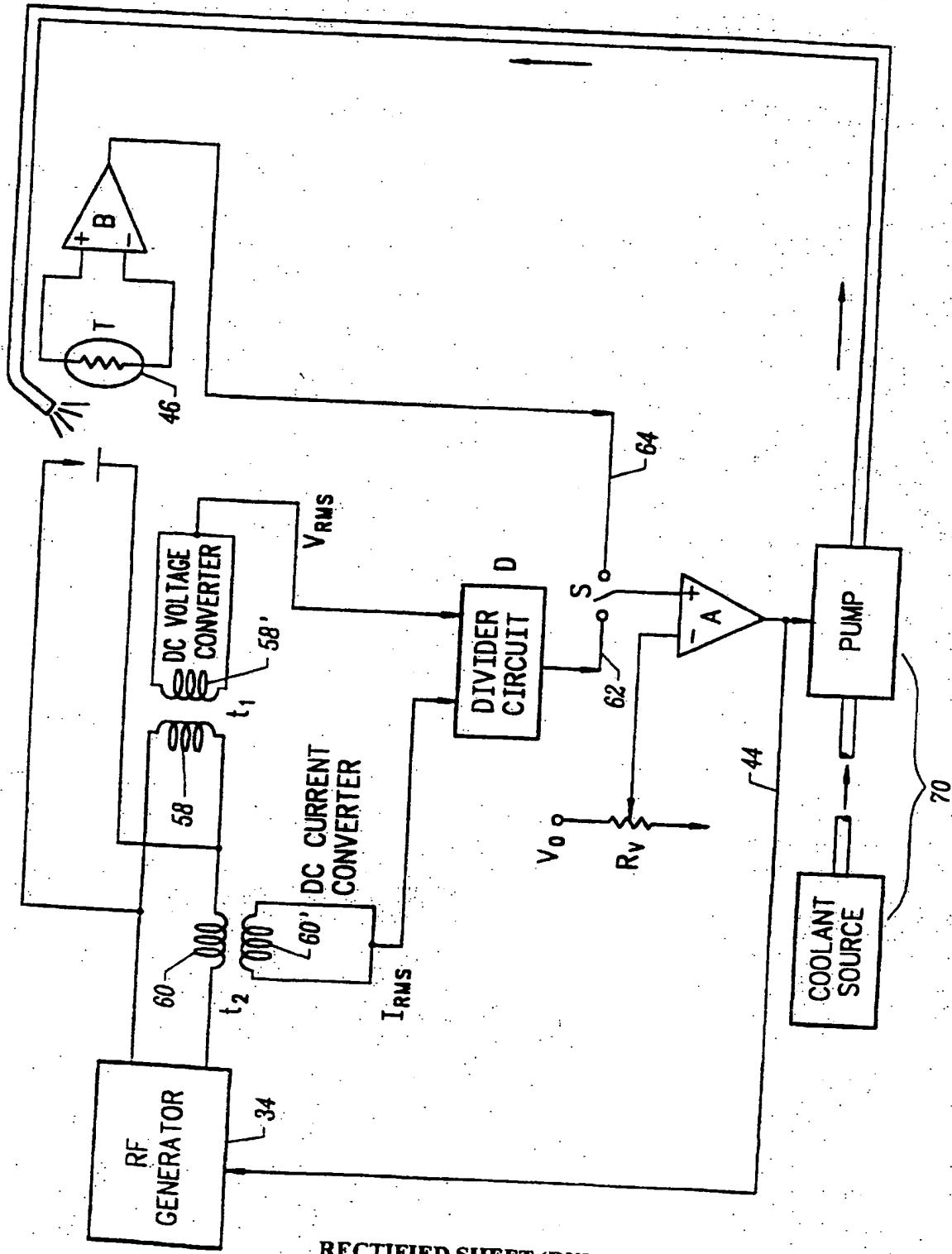


FIG. 16

7/7

FIG. 17



# INTERNATIONAL SEARCH REPORT

Intern 1st Application No

PCT/US 97/13044

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 6 A61N1/40 A61B17/32		
According to International Patent Classification(IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61N A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 395 313 A (NAVES NEIL H ET AL) 7 March 1995 see column 3, line 9 – column 5, line 34; figures	1-10, 14-18
A	US 4 715 372 A (PHILIPP BAR JAY E ET AL) 29 December 1987 see column 4, line 34 – column 5, line 17; figures	1-3, 10-21
<input type="checkbox"/> Further documents are listed in the continuation of box C.		<input checked="" type="checkbox"/> Patent family members are listed in annex.
* Special categories of cited documents :  "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual compilation of the international search	Date of mailing of the international search report	
7 November 1997	17.11.97	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  Rakotondrajaona, C	

# INTERNATIONAL SEARCH REPORT

In. national application No.  
PCT/US 97/13044

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 40-63 because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern.	Application No
	PCT/US 97/13044

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5395313 A	07-03-95	NONE	
US 4715372 A	29-12-87	NONE	

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**